



**IRONSHORE**  
PHARMACEUTICALS & DEVELOPMENT, INC.

FOR IMMEDIATE RELEASE

[www.ironshorepharma.com](http://www.ironshorepharma.com)

**IRONSHORE PHARMACEUTICALS TO SHOWCASE JORNAY PM™  
(METHYLPHENIDATE HCL) CII AT THE 2019 AMERICAN PSYCHIATRIC  
ASSOCIATION MEETING**

***Company to Present Pivotal Trial Data and Sponsor Product Theater***

Research Triangle Park, NC, May 17, 2019 — [Ironshore Pharmaceuticals](http://www.ironshorepharma.com) (“Ironshore”), a leader in the commercialization of novel treatments for Attention Deficit Hyperactivity Disorder (“ADHD”), today announced that it will present data from a pivotal trial of [JORNAY PM™ \(methylphenidate\)](#) extended-release capsules CII at the 2019 American Psychiatric Association (“APA”) meeting in San Francisco, CA, May 18-22, 2019. JORNAY PM (formerly HLD200) is a CNS stimulant approved by the U.S. Food and Drug Administration (“FDA”) for the treatment of ADHD in patients 6 years and older and will be commercially available the first week in June. Attendees are encouraged to visit Ironshore representatives at Booth #319 to learn more about JORNAY PM.

“JORNAY PM is the first and only ADHD stimulant dosed in the evening. Ironshore is proud to share results from the open-label portion of one of the pivotal trials with the psychiatric community,” said Dr. Randy Sallee, Ironshore’s Chief Medical Officer. “For patients with ADHD, the early morning can be particularly challenging. JORNAY PM’s unique delayed-release and extended-release technology is what enables JORNAY PM to be dosed in the evening. When taken the night before, JORNAY PM is designed to provide control of ADHD symptoms in the early morning and throughout the day. JORNAY PM’s unique value proposition – supported by nine clinical studies, including two pivotal trials – represents a welcome addition to the armamentarium of treatment options available for patients with ADHD.”

## **Ironshore-sponsored activities at this year's APA meeting include:**

### *Poster Presentation*

- **Dose Optimization of Evening-Dosed DR/ER-MPH in Children with ADHD: Efficacy and Safety From the 6-Week Open-Label Period of a Phase 3 Classroom Trial**

Monday, May 20, 2019, Poster Session 06, 2:00-4:00PM

*Presenter: Ann Catherine Childress, M.D., President, Center for Psychiatry and Behavioral Medicine, Inc., Las Vegas, NV; investigator in JORNAY PM's pivotal trial program*

### *Product Theater*

- **JORNAY PM: A Novel Delayed-Release and Extended-Release Treatment for ADHD Patients 6 Years and Older**

Monday, May 20, 2019, Exhibit Halls A-C Exhibition Level Moscone Center Product Theater 1, Booth #105, 1:00-2:00PM

*Presenter: Andrew J. Cutler, M.D. Executive Vice President & Chief Medical Officer, Meridien Research, Bradenton, FL; Clinical Professor of Psychiatry, SUNY Upstate Medical University, Syracuse, NY; investigator in JORNAY PM's pivotal trial program\**

To schedule an interview with an investigator or Ironshore executive, please contact Lora Grassilli at [lgrassilli@klcpr.com](mailto:lgrassilli@klcpr.com).



### **WARNING: ABUSE AND DEPENDENCE**

*See full prescribing information for complete boxed warning.*

- CNS stimulants, including JORNAY PM, other methylphenidate-containing products, and amphetamines, have a high potential for abuse and dependence
- Assess the risk of abuse prior to prescribing, and monitor for signs of abuse and dependence while on therapy

*See additional safety information below.*

### **About ADHD**

ADHD is among the most common childhood psychiatric conditions with behavioral symptoms fluctuating throughout the day. It is usually first diagnosed in childhood and often lasts into adulthood. Children with ADHD may have trouble paying attention, controlling impulsive behaviors, or be overly active. Many home-based difficulties for children and adolescents with ADHD occur during the early morning routine (i.e. before the school day begins).

## **About JORNAY PM**

Developed by Ironshore Pharmaceuticals & Development, Inc., JORNAY PM is a central nervous system (CNS) stimulant prescription medicine used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in people 6 years of age and older. JORNAY PM may help increase attention and decrease impulsiveness and hyperactivity in people 6 years of age and older with ADHD. It is not known if JORNAY PM is safe and effective in children under 6 years of age.

JORNAY PM is dosed once daily in the evening and should be initiated at 8:00 p.m. Timing of administration of JORNAY PM may be adjusted between 6:30 p.m. and 9:30 p.m. to optimize the tolerability and the efficacy the next morning and throughout the day. Please see additional dosing information in the full prescribing information for JORNAY PM at <http://ironshorepharma.com/labeling.pdf>.

## **IMPORTANT SAFETY INFORMATION**

### **WARNING: ABUSE AND DEPENDENCE**

CNS stimulants, including JORNAY PM, other methylphenidate-containing products, and amphetamines, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy.

### **CONTRAINDICATIONS**

- Known hypersensitivity to methylphenidate or other components of JORNAY PM. Hypersensitivity reactions such as angioedema and anaphylactic reactions have been reported in patients treated with methylphenidate products.
- Concurrent treatment with a monoamine oxidase inhibitor (MAOI), or use of an MAOI within the preceding 14 days because of the risk of hypertensive crisis.

### **WARNINGS AND PRECAUTIONS**

- *Serious Cardiovascular Reactions:* Sudden death, stroke, and myocardial infarction have been reported in adults treated with CNS stimulants at recommended doses. Sudden death has been reported in pediatric patients with structural cardiac abnormalities and other serious heart problems taking CNS stimulants at recommended doses for ADHD. Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious heart arrhythmias, coronary artery disease, and other serious cardiac problems.

- *Blood Pressure and Heart Rate Increases:* CNS stimulants may cause an increase in blood pressure and heart rate. Monitor all patients for hypertension and tachycardia.
- *Psychiatric Adverse Reactions:* CNS stimulants may exacerbate symptoms of behavior disturbance and thought disorder in patients with a pre-existing psychiatric disorder and may induce a manic or mixed episode in patients with bipolar disorder. In patients with no prior history of psychotic illness or mania, CNS stimulants, at recommended doses, may cause psychotic or manic symptoms.
- *Priapism:* Prolonged and painful erections, sometimes requiring intervention, have been reported with methylphenidate products in both pediatric and adult patients. Priapism has also appeared during a period of drug withdrawal. Immediate medical attention should be sought if signs or symptoms of prolonged penile erections or priapism are observed.
- *Peripheral Vasculopathy, including Raynaud's Phenomenon:* CNS stimulants used to treat ADHD are associated with peripheral vasculopathy, including Raynaud's phenomenon. Careful observation for digital changes is necessary during treatment with ADHD stimulants.
- *Long-Term Suppression of Growth:* CNS stimulants have been associated with weight loss and slowing of growth rate in pediatric patients. Monitor height and weight at appropriate intervals in pediatric patients.

## **ADVERSE REACTIONS**

- Based on accumulated data from other methylphenidate products, the most common (>5% and twice the rate of placebo) adverse reactions for pediatric patients and adults are: appetite decreased, insomnia, nausea, vomiting, dyspepsia, abdominal pain, weight decreased, anxiety, dizziness, irritability, affect lability, tachycardia, and blood pressure increased.
- Additional adverse reactions ( $\geq 5\%$  and twice the rate of placebo) in pediatric patients 6 to 12 years treated with JORNAY PM: headache, psychomotor hyperactivity, and mood swings.

## **PREGNANCY AND LACTATION**

- CNS stimulant medications, such as JORNAY PM, can cause vasoconstriction and thereby decrease placental perfusion.
- The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for JORNAY PM and any potential adverse effects on the breastfed infant from JORNAY PM or from the underlying maternal condition. Monitor breastfeeding infants for adverse reactions, such as agitation, insomnia, anorexia, and reduced weight gain.

Please visit <http://ironshorepharma.com/labeling.pdf> for additional important safety information and the Full Prescribing Information, including Boxed Warning, for JORNAY PM.

**About Ironshore Pharmaceuticals Inc.**

Ironshore Pharmaceuticals Inc. commercializes innovative, patient-centric treatment options to improve the lives of patients and caregivers. Based in North Carolina, Ironshore Pharmaceuticals Inc. is responsible for the sales, marketing and distribution of pharmaceutical products within the US. Ironshore Pharmaceuticals Inc. is a wholly owned subsidiary of Highland Therapeutics Inc. based in Toronto, Canada.

**About Ironshore Pharmaceuticals & Development, Inc.**

Ironshore Pharmaceuticals & Development, Inc., based in Grand Cayman, develops novel therapeutics by leveraging its proprietary drug-delivery technology, DELEXIS®. Ironshore Pharmaceuticals & Development, Inc. is a wholly owned subsidiary of Highland Therapeutics Inc. based in Toronto, Canada.

*\*This is an informational event provided by Ironshore Pharmaceuticals. Participants cannot claim CME credit for attending this informational event and participation may be subject to reporting under the Sunshine Act. The Industry Product Theater's content and the views expressed therein are those of Ironshore Pharmaceuticals and not of APA.*

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**Forward-Looking Statements**

This press release contains forward-looking information, which reflects Ironshore's current expectations regarding future events. Forward-looking information is based on a number of assumptions and is subject to a number of risks and uncertainties, many of which are beyond Ironshore's control that could cause actual results and events to differ materially from those that are disclosed in or implied by such forward-looking information. These forward-looking statements are made as of the date of this press release and, except as expressly required by applicable law, Ironshore assumes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.